

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY	)	MDL NO. 1456
AVERAGE WHOLESALE PRICE	)	Civil Action No. 01-12257
LITIGATION	)	
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THIS DOCUMENT RELATES TO:	)	Judge Patti B. Saris
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<i>The City of New York v. Abbott Laboratories, Inc., et al.</i>	)	
S.D.N.Y. Case No. 04-CV-06054	)	
<i>County of Albany v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0425	)	
<i>County of Allegany v. Abbott Laboratories, Inc., et al.</i>	)	
W.D.N.Y. Case No. 05-CV-0236	)	
<i>County of Broome v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0456	)	
<i>County of Cattaraugus v. Abbott Laboratories, Inc., et al.</i>	)	
W.D.N.Y. Case No. 05-CV-0256	)	
<i>County of Cayuga v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0423	)	
<i>County of Chautauqua v. Abbott Laboratories, Inc., et al.</i>	)	
W.D.N.Y. Case No. 05-CV-0214	)	
<i>County of Chemung v. Abbott Laboratories, Inc., et al.</i>	)	
W.D.N.Y. Case No. 05-CV-6744	)	
<i>County of Chenango v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0354	)	
<i>County of Columbia v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0867	)	
<i>County of Cortland v. Abbott Laboratories, Inc., et al.</i>	)	
N.D.N.Y. Case No. 05-CV-0881	)	
<i>County of Dutchess v. Abbott Laboratories, Inc., et al.</i>	)	
S.D.N.Y. Case No. 05-CV-6458	)	
<i>County of Essex v. Abbott Laboratories, Inc., et al</i>	)	
N.D.N.Y. Case No. 05-CV-0878	)	

**DECLARATION OF JOANNE M. CICALA**  
**IN OPPOSITION TO MOTIONS TO DISMISS**

[Caption Continues on Next Page]

*County of Fulton v. Abbott Laboratories, Inc., et al.* )

N.D.N.Y. Case No. 05-CV-0519	)
<i>County of Genesee v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-00267	)
<i>County of Greene v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0474	)
<i>County of Herkimer v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00415	)
<i>County of Jefferson v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0715	)
<i>County of Lewis v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00714	)
<i>County of Madison v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00714	)
<i>County of Monroe v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6148	)
<i>County of Nassau v. Abbott Laboratories, Inc., et al.</i> )	)
E.D.N.Y. Case No. 04-CV-5126	)
<i>County of Niagara v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-06296	)
<i>County of Oneida v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0489	)
<i>County of Onondaga v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0088	)
<i>County of Ontario v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6373	)
<i>County of Orleans v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6371	)
<i>County of Putnam v. Abbott Laboratories, Inc., et al.</i>	)
S.D.N.Y. Case No. 05-CV-04740	)
<i>County of Rensselaer v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-00422	)
<i>County of Rockland v. Abbott Laboratories, Inc., et al.</i>	)
S.D.N.Y. Case No. 03-CV-7055	)
<i>County of Schuyler v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6387	)
<i>County of Seneca v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6370	)
<i>County of St. Lawrence v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0479	)
<i>County of Saratoga v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0478	)
<i>County of Steuben v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6223	)
<i>County of Suffolk v. Abbott Laboratories, Inc., et al.</i>	)
E.D.N.Y. Case No. 03-CV-12257	)
<i>County of Tompkins v. Abbott Laboratories, Inc., et al.</i>	)

N.D.N.Y. Case No. 05-CV-0397	)
<i>County of Ulster v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0123	)
<i>County of Warren v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0468	)
<i>County of Washington v. Abbott Laboratories, Inc., et al.</i>	)
N.D.N.Y. Case No. 05-CV-0408	)
<i>County of Wayne v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-06138	)
<i>County of Westchester v. Abbott Laboratories, Inc., et al.</i>	)
S.D.N.Y. Case No. 03-CV-6178	)
<i>County of Wyoming v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-6379	)
<i>County of Yates v. Abbott Laboratories, Inc., et al.</i>	)
W.D.N.Y. Case No. 05-CV-06172	)

Joanne M. Cicala, being duly sworn, declares and says:

1. I am a partner at Kirby McInerney & Squire LLP and submit this declaration in opposition to defendants' motion to dismiss the Consolidated Complaint, filed June 15, 2005 (corrected June 22, 2005) (the "CC").

2. I have personal knowledge of the facts sworn to in this declaration which have been developed through investigation and research on behalf of plaintiffs.

3. Attached hereto as Exhibit A is a true and complete copy of the transcript from the April 8, 2005 status hearing.

4. Attached as Exhibit B is a true and complete copy of documentation wherein the State of New York authorizes the instant litigation as a demonstration project pursuant to Section 5 of Part C of Chapter 58 of the Laws of 2005.

5. Attached as Exhibit C is a true and complete copy of the documentation prepared by the New York State Department of Health which expressly "deputizes Kirby McInerney & Squire as representing the State of New York's interests for the purposes of [this] litigation."

6. The CC alleges that defendants manipulate FUL by failing to report true pricing information for the multi-source products. FUL is defined by federal regulation as 150% of the lowest reported price for multi-source therapeutic equivalents. Had defendants reported accurate prices for their multi-source products, the FULs in place for such products would have been lower. CC at ¶86. The support for plaintiffs' allegations at the time of the CC came from a review of certain defendants' actual prices for certain of their multi-source drugs subject to a FUL. In the overwhelming majority of cases we reviewed, the FUL in place for defendants' drug exceeded 150% of the defendants' actual

price for that drug. This meant that defendants did not report their actual prices for their drugs because, had they done so, the FUL would have been lower. Thus, defendants' failure to report their true prices resulted in an inflated FUL and Medicaid overcharge.

7. The CC alleged specific FUL manipulation by those multi-source manufacturers for whom plaintiffs had particular pricing data at the time the CC was filed. *See, for example,* specific FUL allegations for Alpharma at ¶¶207-209; Barr at ¶¶282-284; Boehringer Group at ¶¶353-355 and ¶¶358-359; Endo at ¶¶458-460; Ethex at ¶¶470-472; and Ivax Group at ¶¶537-539.

8. Defendant Sandoz and others who signed on to the Sandoz motion ("the Sandoz defendants") to dismiss attack the CC on the ground that plaintiffs have not explained how their pricing misconduct causes injury where their products are subject to a FUL.<sup>1</sup> Plaintiffs could not provide that detail for the Sandoz Defendants at the time the CC was filed because plaintiffs did not have sufficient data.

9. Through plaintiffs' investigatory efforts, discovery from third parties, the cooperation of numerous State Attorneys General and the federal qui tam relator Ven-a-Care, plaintiffs now have obtained substantially more detailed data in respect of actual generally available market prices, as described below. Even this limited data set demonstrates that every multi-source manufacturer named herein failed to report accurate prices for their therapeutically equivalent multi source drugs, which had the consequence of material inflation of FULs as stated above. Should the Court require such particularity

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<sup>1</sup>Of the 11,418 NDCs listed on Exhibit A to the CC, 5825 of them were at times reimbursed based on a FUL. 5593 were never reimbursed on FUL.

for the Sandoz defendants or any other defendants, plaintiffs seek leave to promptly amend their pleadings to provide such.

10. Below are specific examples of particular evidence with respect to FUL manipulation for the Sandoz defendants .

11. **ABBOTT LABORATORIES, INC.:** Plaintiffs paid for at least 1048 Abbott NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 99 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 99 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 37. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 2% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 62 other Abbott drugs ever subject to a FUL.

12. **ALPHARMA:** Plaintiffs paid for at least 733 Alpharma NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 558 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 558 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 237. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 38% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 321 other Alpharma drugs ever subject to a FUL.

13. **BARR:** Plaintiffs paid for at least 696 Barr NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 516 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 516 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 144. This pricing data reveals that the FULs were 100% to

700% greater than the generally available market prices for at least 27% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 372 other Barr drugs ever subject to a FUL.

14. **BOEHRINGER:** Plaintiffs paid for at least 159 Boehringer NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 21 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 21 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 11. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 36% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 10 other Boehringer drugs ever subject to a FUL.

15. **DEY:** Plaintiffs paid for at least 91 Dey NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 49 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 49 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 21. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 86% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 28 other Dey drugs ever subject to a FUL.

16. **ETHEX:** Plaintiffs paid for at least 142 Ethex NDCs with fraudulently inflated AWPs. Of these, during the relative time period, 23 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 23 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 14. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 57% of such drugs. It

is reasonable to assume that additional market data would reveal similarly inflated FULs for the 9 other Ethex drugs ever subject to a FUL.

17. **Greenstone LTD:** Plaintiffs paid for at least 96 Greenstone NDCs with fraudulently inflated AWPs. Of these, during the relative time period, 67 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 67 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 41. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 10% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 26 other Greenstone drugs ever subject to a FUL.

18. **IVAX:** Plaintiffs paid for at least 1795 Ivax NDCs with fraudulently inflated AWPs. Of these, during the relative time period, 1338 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 1338 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 316. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 67% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 1020 other Ivax drugs ever subject to a FUL.

19. **MYLAN:** Plaintiffs paid for at least 1045 Mylan NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 838 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 838 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 560. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 58% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 278 other Mylan drugs ever subject to a FUL.

20. **PAR:** Plaintiffs paid for at least 723 Par NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 585 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 585 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 178. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 53% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 407 other Par drugs ever subject to a FUL.

21. **PHARMACIA:** Plaintiffs paid for at least 416 Pharmacia NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 69 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 69 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 42. This pricing data reveals that the FULs were 80% to 700% greater than the generally available market prices for at least 2% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 27 other Pharmacia drugs ever subject to a FUL.

22. **ROXANE:** Plaintiffs paid for at least 398 Roxane NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 190 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 190 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 76. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 66% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 114 other Roxane drugs ever subject to a FUL.

23. **SANDOZ:** Plaintiffs paid for at least 1294 Sandoz NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 943 NDCs were

ever subject to a Federal Upper Limit (“FUL”). Of the 943 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 396. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 55% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 547 other Sandoz drugs ever subject to a FUL.

24. **TEVA:** Plaintiffs paid for at least 1294 Teva NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 958 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 958 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 496. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 63% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 462 other Teva drugs ever subject to a FUL.

25. **WARRICK:** Plaintiffs paid for at least 96 Warrick NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 64 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 64 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 33. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 73% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 31 other Warrick drugs ever subject to a FUL.

26. **WATSON:** Plaintiffs paid for at least 1993 Watson NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 1483 NDCs were ever subject to a Federal Upper Limit (“FUL”). Of the 1483 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 776. This pricing data reveals that the

FULs were 100% to 700% greater than the generally available market prices for at least 60% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 707 other Watson drugs ever subject to a FUL.

27. **WYETH:** Plaintiffs paid for at least 985 Wyeth NDCs with fraudulently inflated AWPs. Of these, during the relevant time period, 426 NDCs were ever subject to a Federal Upper Limit ("FUL"). Of the 426 NDCs ever subject to a FUL, plaintiffs now have market pricing data for 160. This pricing data reveals that the FULs were 100% to 700% greater than the generally available market prices for at least 33% of such drugs. It is reasonable to assume that additional market data would reveal similarly inflated FULs for the 266 other Wyeth drugs ever subject to a FUL.

28. I declare under penalty of perjury of the laws of the United States that the foregoing is true and correct.

/s/ Joanne M. Cicala  
Joanne M. Cicala